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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/594,597 | 09/28/2006 | Kazutaka Ikeda | 0649-1380PUS1 | 6839 |
| 2292 7590 07/12/2010 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747 | | | | |
| EXAMINER | | | | |
| KAPUSHOC, STEPHEN THOMAS | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1634 | | | | |
| NOTIFICATION DATE | | DELIVERY MODE | | |
| 07/12/2010 | | ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

**Advisory Action
Before the Filing of an Appeal Brief**

| | |
|--------------------------------------|-------------------------------------|
| Application No. 10/594,597 | Applicant(s) IKEDA ET AL. |
| Examiner STEPHEN KAPUSHOC | Art Unit 1634 |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 June 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none.

Claim(s) objected to: none.

Claim(s) rejected: 1.

Claim(s) withdrawn from consideration: 22 and 23.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Stephen Kapushoc/
Primary Examiner, Art Unit 1634

Continuation of 5. Applicant's reply has overcome the following rejection(s): The rejection of claims under 35 USC 112 2nd paragraph for indefiniteness, as set forth on pages 5-6 of the Office Action of 03/19/2010.

Continuation of 11. does NOT place the application in condition for allowance because:

Applicants' Remarks (06/21/2010) in view of the amendments have been fully and carefully considered but are not found to be persuasive to withdraw the objections to the amendments to the specification (as set forth on pages 3-4 of the Office Action of 03/19/2010) and the rejection of claims under 35 USC 112 1st paragraph for lack of enablement (as set forth on pages 6-13 of the Office Action of 03/19/2010).

Applicants have requested rejoinder (p.9 of Remarks) of the subject matter of claims 22 and 23 with the subject matter of the Elected invention. However, because claim 1 (which encompasses the elected SNP at IVS3+6151) is not yet found allowable, rejoinder of the non-elected subject matter at this time is premature. Upon allowance of claims drawn to the elected subject matter, claims which require all of the limitations of any such allowed claims will be rejoined with the allowed claims.

Applicants have asserted that the Amendments to the specification, as objected to in the Office Action of 03/19/2010, are adequately supported by the specification as originally filed. The Examiner maintains (with regard to Table 4) that while the specification may generically support oligonucleotides have 101 bases, such generic support does not provide for the particular oligonucleotide set forth as SEQ ID NO: 100, where the specification does not provide support for the particular sequence elements required of the newly added oligonucleotide. Further, with regard to Table 6, the Examiner maintains that where applicants have not provided any of the data used to calculate linkage disequilibrium, there is not sufficient basis to support the argument that particular linkage disequilibrium values are 'inherent in the population described in the present application' (p10 of Remarks). As such the objections to the amendments to the specification (as set forth on pages 3-4 of the Office Action of 03/19/2010) are maintained.

Applicants have argued (p.11-13 of Remarks) that the methods of the amended claims are enabled by the teachings of the specification. Applicants' arguments have been fully and carefully considered but are not found to be persuasive. Applicants have argued that the data of Table 10 demonstrates an association between the elected SNP and methamphetamine use. The Examiner maintains that in analyzing the totality of the data of the instant specification, one must also consider Table 7, which teaches less than significant associations between the Elected SNP and methamphetamine addiction, and Table 8, which shows that in haplotype 5 and 6, which comprises IVS3+6151 A and G, respectively, there is a non significant trend in both haplotypes (i.e. haplotypes with each allele of the SNP) for overrepresentation in MAP subjects. Thus the examiner maintains that in the analysis of all the relevant data, the skilled artisan would not reach the conclusion that a robust and reliable relationship between the required IVS3+6151 SNP and methamphetamine sensitivity exists. The rejection as it applies to the pending claims is maintained.